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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,757	09/15/2003	Michael S. Williams	9362-3	1920

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EXAMINER	
LIN, JAMES	

ART UNIT	PAPER NUMBER
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,757	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Jimmy Lin	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45 and 72* is/are pending in the application.

4a) Of the above claim(s) *4,5,11,14,18-30,34,41 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-10,12,13,15-17,31-33,35-40,42,43,45 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 11/22/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,932,930 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2, 6-10, 13, 15-16, 31-32, 35-40, 43, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki et al. (WO 2002/43799, references made are to the English equivalent U.S. Publication 2003/0104030) in view of Guruwaiya et al. (U.S. Patent 6,251,136).

Igaki discloses a method of impregnating a stent with a pharmacological agent (abstract), the method comprising:

immersing a stent comprising a polymeric material in a mixture of a carrier fluid and a pharmacological agent [0052];

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the polymeric material [0057];

removing the pressure such that the carrier fluid diffuses out of the polymeric material [0062] and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material [0011].

Igaki does not explicitly teach the step of masking the stent. However, Guruwaiya teaches a method of coating a pharmacological agent on a stent (abstract), wherein certain portions of the stent is masked during the coating process. The mask is used to selectively coat the stent in order to achieve a specific effect when using the stent for its intended purpose (col. 2, lines 49-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have masked certain portions of the stent of Igaki with a reasonable expectation of success. One would have been motivated to do so in order to have achieved a specific effect as described in Guruwaiya. The mask is then removed after the coating of the pharmacological agent because the mask is not part of the final product.

Claim 31: The stent is placed in a pressure vessel 27 [0057] and the polymer can be formed only on the surface of the stent [0067]. The pressure vessel is set to a pressure between 7.38-24 MPa [0058].

Claims 2,6,32,36: Supercritical carbon dioxide is the carrier fluid [0052]-[0058].

Claims 7,9,37,39: Ethanol can be used as a co-solvent [0053].

Claims 8,38: The carrier fluid is used to cause the polymer to become swollen [0063], thereby altering the diffusion coefficients of the polymeric material.

Claims 10,40: The intraluminal prosthesis is a stent (abstract).

Claims 13,43: The polymer can be formed only on the surface of the stent [0067].

Claims 15,16: The pressure is controlled in the step of removing pressure [0062].

Claim 35: The pressure vessel can be pressurized with carbon dioxide [0057].

Claim 72: Guruwaiya teaches that two different portions of the stent can be coated with two different pharmacological agents (col. 4, lines 58-62), thus requiring a first masking step to apply the first pharmacological agent and a second masking step to apply the second pharmacological agent. Therefore, it would have been obvious to one of ordinary skill in the art

at the time of invention to have masked first and second portions and to have applied a first and a second pharmacological agent to the unmasked regions of Igaki in order to have manufactured a stent having two different effects.

5. Claims 3 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki '799 in view of Guruwaiya '136 as applied to claims 2 and 32 above, and further in view of Edwards et al. (U.S. Patent 6,670,398).

Igaki and Guruwaiya are discussed above, but do not teach the use of everolimus as the pharmacological agent. However, Edwards teaches everolimus is a therapeutic drug that can be used to suppress the transplant recipient's immune response against the transplanted organ or tissue (col. 2, lines 3-10). Everolimus can be coated onto a stent (col. 21, lines 8-39). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have impregnated everolimus as the particular pharmacological agent onto the stent of Igaki with a reasonable expectation of success because Edwards teaches that it is suitable to administer everolimus using a stent and because one would have been motivated to do so in order to provide stent for use in organ or tissue transplant.

6. Claims 12 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki '799 in view of Guruwaiya '136 as applied to claims 1 and 31 above, and further in view of Mehta et al. (WO 01/87368).

Igaki and Guruwaiya are discussed above, but do not explicitly teach the polymeric material can be non-erodible. However, Igaki does teach the desire to control the release of the drug into the target site [0011]. Mehta teaches a method of making a stent, wherein the stent is coated with a polymer and a pharmacological agent (pg. 7, lines 12-29). The polymeric material can be either biostable (i.e., non-erodible) or bioabsorbable (i.e., erodible) depending on the desired rate of release (pg. 8, lines 9-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a biostable polymer in the process of

making the stent of Igaki. One would have been motivated to do so in order to have controlled the rate of release of the pharmacological agent.

7. Claims 17 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki '799 in view of Guruwaiya '136 as applied to claims 1 and 31 above, and further in view of Ragheb et al. (U.S. Patent 6,299,604).

Igaki and Guruwaiya are discussed above. Igaki teaches herapin as an example of a pharmacological agent [0050], but does not explicitly teach using a radiopaque material. However, Ragheb teaches that a radiopaque material is a suitable alternative to herapin for use in the vascular system. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a radiopaque material as the particular pharmacological agent with a reasonable expectation of success because Ragheb teaches that radiopaque materials are suitable pharmacological agents that can be used in the vascular system.

Response to Arguments

8. Applicant's arguments with respect to claims 1-3, 6-10, 12-13, 15-17, 31-33, 35-40, and 42-43, and 45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mehta et al. (U.S. Publication 2002/0051845) teaches a method of impregnating a stent.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
JL

KEITH HENDRICKS
PRIMARY EXAMINER